

REMARKS

The Final Office Action of April 5, 2005, has been received and reviewed.

Claims 34-70 and 72-120 are currently pending and under consideration in the above-referenced application. It has been indicated that claims 100-109 are allowed and that claims 43, 46, 48-51, 61, 62, 65-69, 75, 78, 80-83, 85-87, 95-99, 111, and 116-120 recite allowable subject matter. Each of claims 34-42, 44, 45, 47, 52-60, 63, 64, 70, 72-74, 76, 77, 79, 84, 88-94, 110, and 112-115 stands rejected.

Reconsideration of the above-referenced application is respectfully requested.

Rejections Under 35 U.S.C. § 102

Claims 34-42, 44, 45, 47, 52-60, 63, 64, 70, 72-74, 76, 77, 79, 84, 88-94, 110, and 112-115 stand rejected under 35 U.S.C. § 102(e) for reciting subject matter which is purportedly anticipated by that described in U.S. Patent 6,200,271 to Kück et al. (hereinafter “Kück”).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference which qualifies as prior art under 35 U.S.C. § 102. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Kück, at col. 9, lines 31-42, describes an exemplary “bi-directional rebreathing” process that includes a “before” phase that last for six seconds (the difference between the time at 40 seconds into the process and the time at 46 seconds into the process). The subsequent “during” phase lasts for about 50 seconds. Col. 9, lines 43-51. Kück is silent as to the specific length of the “after” phase, which occurs following the “during” phase. See Col. 9, lines 52-60 (which merely states that the “after” phase “may be of any duration sufficient to facilitate the accurate determination of VCO₂ and CACO₂”).

The Office has also noted that Figs. 4 and 5 of Kück show a “before rebreathing” phase that during which respiration is evaluated for about 50 seconds, a “during rebreathing” phase that

lasts for about 60 seconds, and an “after rebreathing” phase in which rebreathing is monitored for about 40 seconds.

With respect to the subject matter recited in independent claim 34, as proposed to be amended herein, Kück lacks any express or inherent description of a method which includes evaluating respiration during first and second ventilation states that each last for approximately 18 seconds to approximately 42 seconds. Instead, the description of Kück is limited to evaluating respiration for a first state that lasts for six seconds (which is one-third of 18 seconds and, thus, is not *approximately* 18 seconds), a second state that lasts for about 50 seconds (which is about 20% greater than 42 seconds and, thus, is not *approximately* 42 seconds), and a third state that lasts for an undefined period of time, or to evaluating respiration for first, second, and third states that respectively last for 50 seconds (which is greater about 20% greater than 42 seconds and, thus, is not *approximately* 42 seconds), 60 seconds (which is about 35% greater than 42 seconds and, thus, is not *approximately* 42 seconds), and 40 seconds.

Therefore, Kück does not anticipate each and every element of any of amended independent claim 34. Accordingly, it is respectfully submitted that, under 35 U.S.C. § 102(e), amended independent claim 34 recites subject matter which is allowable over that described in Kück.

Each of claims 35-42, 44, 45, and 47 is allowable, among other reasons, for depending directly or indirectly from claim 34, which is allowable.

Claim 36 is additionally allowable since Kück does not expressly or inherently describe “repeating evaluating respiration of [a] subject during another first ventilation state *immediately following* evaluating respiration of the subject during [a] second ventilation state.” (Emphasis supplied). Instead, Kück describes evaluating respiration of a subject during a first state (the “before” phase), then a second state (the “during” phase), then a third state (the “after” phase) before repeating the first state of the three-state process.

Claim 45 is further allowable because Kück includes no express or inherent description of evaluating respiration of a subject during a second ventilation state in which the subject breathes “gas or a gas mixture comprising at least a concentration of oxygen present in air.” Instead, the

description of Kück is limited to a second ventilation state in which a subject breathes gases with an increased concentration of carbon dioxide.

Independent claim 52 is drawn to a method for noninvasively estimating at least one of a pulmonary capillary blood flow and a cardiac output of a patient. The method of independent claim 52 includes evaluating respiration of a patient during first and second ventilation states. The second ventilation state immediately follows the first ventilation state. Then, immediately following the second ventilation state, respiration of the patient is evaluated during another first ventilation state. Independent claim 52, as proposed to be amended herein, also recites that each of the first, second, and another first ventilation states has a duration of approximately 18 seconds to approximately 42 seconds.

Kück does not expressly or inherently describe a process in which a first ventilation state is followed by a second ventilation state, which is immediately followed by another first ventilation state. Rather, in the process of Kück, a first ventilation state is followed by a second ventilation state, then by a third ventilation state. If that process were repeated, the third ventilation state would be followed by another first ventilation state.

Assuming, solely for the sake of argument, that the first and third ventilation states of Kück could be considered to comprise a single ventilation state, these ventilation states would have an indeterminate duration (*i.e.*, six seconds plus an indeterminate amount of time is still equal to an indeterminate amount of time) or a duration of 90 seconds (*i.e.*, 40 seconds plus 50 seconds), neither of which falls within the approximately 18 seconds to approximately 42 seconds range recited in amended independent claim 52.

When the three ventilation states of Kück are considered separately, no combination of two adjacent-in-time ventilation states meets the duration requirements of amended independent claim 52. Specifically, the description of Kück is limited to evaluating respiration for a first state that lasts for six seconds (which is one third of 18 seconds and, thus, is not *approximately* 18 seconds) or 50 seconds (which is about 20% more than 42 seconds and, thus, not *approximately* 42 seconds), a second state that lasts for about 50 seconds (which is about 20% greater than 42 seconds and, thus, is not *approximately* 42 seconds) or 60 seconds

(which is about 35% greater than 42 seconds and, thus, is not *approximately* 42 seconds), and a third state that lasts for an indeterminate period of time or 40 seconds.

For these reasons, Kück does not anticipate each and every element of amended independent claim 52 in the arrangement required by amended independent claim 52. Therefore, it is respectfully submitted that, under 35 U.S.C. § 102(e), amended independent claim 52 recites subject matter which is allowable over that taught in Kück.

Each of claims 53-60, 63, and 64 is allowable, among other reasons, for depending either directly or indirectly from claim 52, which is allowable.

Claim 53 is also allowable since Kück neither expressly nor inherently describes that first and second ventilation states may be effected for substantially a same duration. Rather, the disclosure of Kück is limited to one technique in which a “before” phase lasts for six seconds, a “during” phase lasts for about 50 seconds (which is significantly greater than six seconds), and an “after” phase lasts for an indeterminate period of time, and to another technique in which the 60 second “during” phase is longer than both the 50 second “before” phase and the 40 second “after” phase.

Claim 54 is further allowable since Kück does not expressly or inherently describe that respiration may be evaluated during first, second, and another first ventilation states having substantially the same durations. Instead, Kück describes that respiration may be evaluated during a first state that lasts for six seconds, a second state that lasts for about 50 seconds, and a third state that lasts for an indeterminate period of time, or that respiration may be evaluated during a first state that lasts for 50 seconds and a second state that lasts for 60 seconds, and a third state that lasts for 40 seconds.

Claims 55-57 are allowable because Kück includes no express or inherent description that respiration may be respectively evaluated during a first, second, or another first ventilation state that lasts for about thirty seconds. Rather, the description of Kück is limited to a first ventilation state that for six seconds or 50 seconds and a second ventilation state lasts for about 50 seconds or for 60 seconds, none of which is even close to 30 seconds.

Claim 64 is further allowable because Kück includes no express or inherent description of evaluating respiration of a patient during a second ventilation state in which the patient breathes

“gas or a gas mixture comprising at least a concentration of oxygen present in air.” Instead, the description of Kück is limited to a second ventilation state in which a patient breathes gases with an increased concentration of carbon dioxide.

Independent claim 70 is directed to a differential Fick technique that *consists essentially of* (i.e., includes no essential elements other than) a first phase, in which a change in effective ventilation of a subject is induced, and a second phase that follows the first phase and during which the change in effective ventilation is not present. Kück does not expressly or inherently describe a differential Fick technique that *consists essentially of* two phases of substantially the same duration. Instead, the process described in Kück includes three phases. These include a first (“before”) phase, a second (“during”) phase, and a third (“after”) phase, which respectively occur before, during, and after a change in effective ventilation, such as rebreathing.

Therefore, it is respectfully submitted that the description provided by Kück does not anticipate each and every element of independent claim 70, as would be required to maintain the 35 U.S.C. § 102(e) rejection of that claim.

Claims 72-74, 76, 77, and 79 are each allowable, among other reasons, for depending directly from claim 70, which is allowable.

Claim 72 is also allowable because Kück lacks any express or inherent description of first and second phases that both have durations of about thirty seconds. Rather, Kück describes a process in which a “before” phase lasts for six seconds, a “during” phase lasts for about 50 seconds, and an “after” phase lasts for an indeterminate period of time, and to a process in which a “before” phase lasts for 50 seconds and a “during” phase lasts for 60 seconds, and an “after” phase lasts for 40 seconds. All of these time periods differ significantly from the “about thirty seconds” required by claim 72.

Independent claim 84 is also directed to a differential Fick technique. The differential Fick technique of independent claim 84, as amended and presented herein, includes inducing a change in effective ventilation of an individual for a duration of time of approximately 18 seconds to approximately 42 seconds. The change in effective ventilation is

then removed for a second duration of time, which lasts for approximately 18 seconds to approximately 42 seconds. The second duration of time immediately follows the first duration of time. In addition, measurements of at least one respiratory gas and of respiratory flow are obtained during both the first duration and the second duration.

Kück includes no express or inherent description of a Fick technique that includes inducing a change in effective ventilation for a first duration of time, which lasts for approximately 18 seconds to approximately 42 seconds, removing the change in effective ventilation for a second duration of time, which also lasts for approximately 18 seconds to approximately 42 seconds, and obtaining gas and flow measurements during both the first and second durations of time. Instead, Kück merely describes a “during” rebreathing phase that lasts for about 50 seconds or for 60 seconds, both of which are well outside of the approximately 18 seconds to approximately 42 seconds range recited in amended independent claim 84.

As Kück does not anticipate each and every element of amended independent claim 84, it is respectfully submitted that, under 35 U.S.C. 103(a), amended independent claim 84 is directed to subject matter which is allowable of that described in Kück.

Claims 88-94 are each allowable, among other reasons, for depending either directly or indirectly from claim 84, which is allowable.

Claim 88 is also allowable since Kück neither expressly nor inherently describes that a first duration of time of inducing a change in effective ventilation and a second duration of time of removing a change in effective ventilation may substantially be the same.

Claim 91 is also allowable since Kück does not expressly or inherently describe that a change in effective ventilation may be induced for about thirty seconds and removed for about thirty seconds. Instead, Kück teaches that a “before rebreathing” state lasts for six seconds or 50 seconds and that a “rebreathing” state lasts for 50 seconds or 60 seconds, and that an “after rebreathing” state, or recovery period, that follows the “rebreathing state” may last for an indeterminate period of time or for 40 seconds.

Independent claim 110 also recites a method for noninvasively determining at least one of a pulmonary capillary blood flow and a cardiac output of a patient. The method of independent

claim 110 includes evaluating respiration of the patient during each of a first phase and a second phase. During the first phase, which lasts for a first duration of time, a change in effective ventilation of the patient is induced. During the second phase, which lasts for a second period of time, the change in effective ventilation is removed. Independent claim 110, as proposed to be amended herein, also recites that the first and second phases each last for approximately 18 seconds to approximately 42 seconds.

Kück includes no express or inherent description of a method that includes evaluating respiration during a ventilation phases in which a change in effective ventilation of a subject is induced for a period of time lasting from approximately 18 seconds to approximately 42 seconds. Instead, with respect to rebreathing (a type of change in effective ventilation), the disclosure of Kück is limited to a duration of about 50 seconds or 60 seconds, which is well outside of the approximately 18 seconds to approximately 42 seconds range recited in amended independent claim 110.

Therefore, Kück does not anticipate each and every element of amended independent claim 110. It is, therefore, respectfully submitted that, under 35 U.S.C. § 102(e), amended independent claim 110 recites subject matter which is allowable over that described in Kück.

Claims 113-115 are each allowable, among other reasons, for depending directly or indirectly from claim 110, which is allowable.

In view of the foregoing, it is respectfully requested that the 35 U.S.C. § 102(e) rejections of claims 34-42, 44, 45, 47, 52-60, 63, 64, 70-74, 76, 77, 79, 84, 88-94, 110, and 112-115 be withdrawn.

Rejections Under 35 U.S.C. § 102(e) or 103(a)

Claims 34, 35, 37-42, 44, 45, 47, 70, 72-74, 76-77, and 79 have been rejected for reciting subject matter that is allegedly anticipated under 35 U.S.C. § 102(e) or, alternatively, unpatentable under 35 U.S.C. § 103(a) over the subject matter disclosed in U.S. Patent 6,106,480 to Gama De Abreu et al. (hereinafter “Gama De Abreu”).

The standard for establishing and maintaining a rejection under 35 U.S.C. § 103(a) is set forth in M.P.E.P. § 706.02(j), which provides:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Gama De Abreu describes techniques for noninvasively determining pulmonary cardiac blood flow by measuring CO₂ elimination (VCO₂) and end-tidal, or expiration termination, CO₂ partial pressure (PetCO₂) over the final 60 seconds of a nonbreathing period, the length of which is not identified in Gama De Abreu, and over the final 15 seconds of a 30 second rebreathing period. Col. 2, lines 40-57. It is apparent from the graph of FIG. 4 of Gama De Abreu that the final 60 seconds of nonbreathing during which measurements are obtained is not the entire nonbreathing period, as the graph does not show any recovery (which would likely last at least 15 seconds; *see* col. 4, lines 8-11) before the part of the nonbreathing period that is shown in the graph.

Independent claim 34 is directed to a method which includes “evaluating respiration of [a] subject during a first ventilation state” and “evaluating respiration of the subject during a second ventilation state.” As amended and presented herein, the first and second ventilation states that are recited in independent claim 34 both have durations of “approximately eighteen to approximately forty-two seconds.”

Gama De Abreu does not expressly or inherently describe first *and* second ventilation status that both have durations of approximately 18 seconds to approximately 42 seconds. Rather, the description of Gama De Abreu is limited to a nonbreathing period that lasts for significantly more than 60 seconds, which is significantly (about 35%) greater than

approximately 42 seconds, and a 30 second rebreathing period. As such, Gama De Abreu does not anticipate or render unpatentable each and every element of amended independent claim 34.

It is, therefore, respectfully submitted that the subject matter to which amended independent claim 34 is directed is allowable over the subject matter described in Gama De Abreu.

Claims 35, 37-42, 44, 45, and 47 are each allowable, among other reasons, for depending directly from claim 34, which is allowable.

Independent claim 70 recites a differential Fick technique that includes a first phase in which a change in the effective ventilation of a subject is induced and a second phase, which follows the first phase, of substantially the same duration as the first phase and in which a change in effective ventilation is not present.

In contrast to the subject matter recited in independent claim 70, the disclosure of Gama De Abreu is limited to a process in which VCO₂ and PetCO₂ are monitored during a first, nonrebreathing period (*i.e.*, a period in which there is no change in effective ventilation of a subject), which is followed by a second rebreathing period (*i.e.*, a period in which a change in effective ventilation is induced).

Moreover, Gama De Abreu lacks any express or inherent description that the nonrebreathing and rebreathing periods mentioned therein have substantially the same durations. Rather, the nonrebreathing period of Gama De Abreu lasts for significantly more than 60 seconds, while the rebreathing period lasts for only 30 seconds.

For these reasons, Gama De Abreu does not anticipate each and every element of independent claim 70, as would be required to maintain the 35 U.S.C. § 102(e) rejection thereof, or teach or suggest each and every element of independent claim 70, as would be required to establish a *prima facie* case of obviousness against independent claim 70 under 35 U.S.C. § 103(a).

Each of claims 72-74, 76, 77, and 79 is allowable, among other reasons, for depending directly from claim 70, which is allowable.

Claim 72 is further allowable since Gama De Abreu includes no express or inherent description or teaching or suggestion that the nonbreathing period thereof has a duration of about 30 seconds. Rather, the description of Gama De Abreu is limited to a technique that includes a nonbreathing period that lasts for significantly more than 60 seconds.

It is further submitted that one of ordinary skill in the art would not have been motivated to modify the subject matter taught in Gama De Abreu in the manner that has been asserted. In particular, the Office has not identified any teaching or suggestion in Gama De Abreu or the art that was generally available to those of ordinary skill in the art before the above-referenced application was filed that would have motivated one of ordinary skill in the art to significantly reduce the nonbreathing period of Gama De Abreu. Based on the lack of such a showing, it appears that the only source for such motivation would have been improper reliance upon the subject matter disclosed and claimed in the above-referenced application.

Accordingly, withdrawal of the 35 U.S.C. § 102(e) and 35 U.S.C. § 103(a) rejections of claims 34, 35, 37-42, 44, 45, 47, 70, 72-74, 76-77, and 79 is respectfully requested.

Entry of Amendments

Entry of the proposed claim amendments is respectfully requested. The proposed amendments to the claims do not introduce new matter into the above-referenced application, nor will they require and additional search.

In the event that the proposed claim amendments are not entered, entry thereof is respectfully solicited upon the filing of a Notice of Appeal in the above-referenced application.

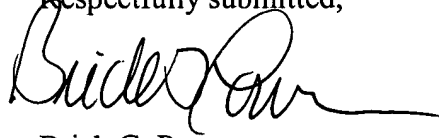
CONCLUSION

It is respectfully submitted that each of claims 34-70 and 72-120 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing

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allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Brick G. Power", with a long horizontal flourish extending to the right.

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